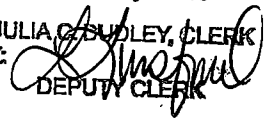


Exhibit 2

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
AT ABINGDON

CLERK'S OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED

JUL 26 2016

JULIA G. DUDLEY, CLERK
BY:  DEPUTY CLERK

UNITED STATES OF AMERICA :

v. :

Case No. 1:16CR00034

Violations: 18 U.S.C. §§ 371, 1341 & 1349

SITESH BANSI PATEL and
GUILLERMO "WILLY" RAMOS :

INDICTMENT

INTRODUCTION

The Grand Jury charges that at all times relevant to this Indictment:

1. The United States Food and Drug Administration (FDA) was an agency of the United States government responsible for enforcing the provisions of the Federal Food, Drug and Cosmetic Act (FDCA), Title 21, United States Code, Section 301, *et seq.* The FDA's responsibilities included, among other things, regulating the distribution of drugs shipped, delivered and received in interstate commerce.
2. The FDCA defined the term "drug," as "(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)." 21 U.S.C. § 321(g)(1).

3. The FDCA defined a “new drug” as any drug “the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. . . .” 21 U.S.C. § 321(p)(1). In order to be lawfully marketed, sold or dispensed in the U.S., a new drug had to be the subject of a New Drug Application which had been approved by the FDA. 21 U.S.C. § 355.
4. The FDCA defined the term “food” to include articles that (1) were used for food or drink for man; (2) were used for components of any such article. 21 U.S.C. §§ 321(f)(1) and (3).
5. Under the FDCA, a “dietary supplement” was deemed to be a food. The FDCA defined the term “dietary supplement” to mean a product intended to supplement the diet that contained one or more specified ingredients and, among other things, was labeled as a dietary supplement. A dietary supplement must contain one or more “dietary ingredients”. A dietary ingredient is a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of one or more of these dietary ingredients. A product was not considered a dietary supplement if it contained a synthetic steroid, including substances known as “pro-hormones.”
6. Pro-hormones are a classification of precursor drugs of anabolic steroids like testosterone, which are taken to boost the body’s available hormone supply. These precursors are intended to be converted to full, active hormones via an enzymatic process that occurs during metabolism. Pro-hormones are used mainly by athletes for the purpose of increasing size, strength, endurance, recovery time or to add lean body mass. They are most used for

increasing muscle mass or reducing body fat levels. Pro-hormones have similar side-effects to anabolic steroids

7. The FDCA defined the term “labeling” as “all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article”. 21 U.S.C. § 321(m).
8. The FDCA defined the term “interstate commerce” as “(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.” 21 U.S.C. § 321(b).
9. SITESH BANSI PATEL was vice-president of SK Labs, Inc., 1173 North Grove Street, Anaheim, CA 92806.
10. GUILLERMO “WILLY” RAMOS was president of Human Tech Sport Nutrition Company, 3516 Seagate Way, Oceanside, CA 92056.
11. Steve Wood was the president and owner of Competitive Edge Labs, LLC, 3801 U.S. Highway 29 North, Danville, VA. He also controlled MKZ Exports, LLC.
12. Neither GUILLERMO “WILLY” RAMOS nor Human Tech Sport Nutrition were registered with the FDA as a manufacturing facility for drugs.
13. The Conspirators did not provide a list of the manufactured drugs to the FDA as required by 21 U.S.C. §360(j).
14. The product labeled “M-Drol” listed its single active ingredient as 2alpha, 17alpha-dimethyl etiocholan-3-one, 17 beta-ol, a chemical name for methasterone. Methasterone is a “designer steroid” or “designer drug”, a structural or functional analog of a controlled substance designed to mimic the pharmacological effects of the original drug. This product was and was intended to be used as a drug and was not a vitamin, mineral, amino acid, herb or other

botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Further, it was not a concentrate, metabolite, constituent, extract or combination of any such dietary ingredient.

15. The product labeled "H-Drol" listed its single active ingredient as "4chloro, 17alpha, methyl androst 1,4-diene-3,17beta-diol, the chemical name for a designer drug identified as halovar, a clone of halodrol. This product was a drug and not a vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Further, it was not a concentrate, metabolite, constituent, extract or combination of any such dietary ingredient.
16. M-Drol and H-Drol labels were false and misleading in that they claimed the products were the more lightly regulated dietary supplements but, in fact, were intended to be used as drugs.
17. M-Drol and H-Drol were misbranded drugs because:
 - a. their labeling was false and misleading in any particular (21 U.S.C. § 352(a));
 - b. in package form, their labels did not contain the (1) name and place of business of the manufacturer, packer or distributor (21 U.S.C. § 352(b));
 - c. their labeling did not bear (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health (21 U.S.C. § 352(f)); and
 - d. they were manufactured, prepared, propagated, compounded, or processed in an establishment in any state not duly registered under 21 U.S.C. § 360 and they were not included in a list required by 21 U.S.C. § 360(j) (21 U.S.C. § 352(o)).

COUNT ONE

The Grand Jury charges that:

1. The Introduction is realleged and incorporated by reference.
2. At times from in or about 2008 through in or about August 2011, in the Western District of Virginia and elsewhere, SITESH BANSI PATEL, GUILLERMO “WILLY” RAMOS, Steve Wood and others (“Conspirators”), knowingly conspired to
 - a. commit an offense against the United States, that is, with the intent to defraud and mislead to:
 - i. introduce and deliver for introduction into interstate commerce a drug that was misbranded, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2);
 - ii. Receive in interstate commerce a drug that was misbranded, in violation of 21 U.S.C. §§ 331(c) and 333(a)(2); and
 - iii. Fail to register in accordance with 21 U.S.C. § 360 and fail to provide any information required by 21 U.S.C. § 360(j), in violation of 21 U.S.C. §§ 331(p) and 333(a)(2); and
 - b. defraud the United States by impeding, impairing, obstructing, and defeating the lawful functions of the Food and Drug Administration of the Department of Health and Human Services in regulating drugs for use by humans.
3. To effect the object of the conspiracy, the Conspirators did several acts in the Western District of Virginia and elsewhere, including, but not limited to, the following:
 - a. Steve Wood illegally imported raw drug components (raw drug powders) from China for the purpose of manufacturing drugs marketed as “M-Drol” and “H-Drol”.

- b. In or about 2008 and 2009, Steve Wood caused the raw drug powders to be shipped to SK Labs Inc, in California. SK Labs then encapsulated and bottled M-Drol and H-Drol and shipped the product to Wood in the Western District of Virginia. At some point, SK Labs ceased manufacturing M-Drol and H-Drol for Wood.
- c. In or about December 2010, Steve Wood contacted SITESH BANSI PATEL, of SK Labs, and requested that PATEL restart the manufacture of M-Drol and H-Drol. SITESH BANSI PATEL indicated he did not want his company, SK Labs Inc., to be involved in this activity but agreed to locate someone that could do so.
- d. SITESH BANSI PATEL subcontracted with GUILLERMO "WILLY" RAMOS to manufacture the M-Drol and H-Drol capsules for Steve Wood.
- e. Steve Wood paid GUILERRMO "WILLY" RAMOS \$2.30 per bottle for encapsulating the product M-Drol and \$2.15 per bottle for encapsulating the product H-Drol.
- f. On certain dates from December 2010 through August 2011, GUILLERMO "WILLY" RAMOS manufactured 40,676 bottles of M-Drol and H-Drol capsules in California and shipped them to Steve Wood in Virginia.
- g. Steve Wood caused the sending of cash payments of approximately \$16,000 to SITESH BANSI PATEL as a finder's fee for locating GUILERRMO "WILLY" RAMOS to manufacture these products.
- h. On or about December 8, 2010, SITESH BANSI PATEL sent an email to Steve Wood stating *"I know they are also involved in the otherside of the business (hint hint) so I'm sure the PH [prohormone] thing is something they are used to."*

- i. On or about December 8, 2010, SITESH BANSI PATEL sent an email to Steve Wood stating *"Let me know how the first run goes. I will work directly with him [GUILLERMO RAMOS] to make sure it goes smooth (overview the formulation, etc.) As for the compensation I really don't care if it works out and the contact is beneficial to you, whatever you think is cool is cool with me."*
- j. On or about December 8, 2010, SITESH BANSI PATEL told Steve Wood that he located a manufacturer and in a three-way email exchange introduced the manufacturer named GUILLERMO "WILLY" RAMOS, and stated in part *"... I would like to take this email to introduce you two. Willy: Steve is one of my good customers and is looking for someone to manufacture some products for him as we discussed over the phone... The product will be: 10mg, 90 capsules bottle..."* further identified as M-Drol.
- k. On or about December 8, 2010, SITESH BANSI PATEL drafted an email to Steve Wood and GUILLERMO "WILLY" RAMOS which stated in part *"for that 60ct job, 15,000 bottles = 900,000 capsules, said he [RAMOS] can turn it around in under 2 weeks"*. This was the product H-Drol.
- l. In or about December 2010, SITESH BANSI PATEL and Steve Wood agreed to have the material (payment, bottle labels, raw drug powders), shipped directly to SITESH BANSI PATEL for the first few orders to make sure everything worked out.
- m. In or about December 2010, Steve Wood caused 10 kilograms of raw drug powder to be sent to SITESH BANSI PATEL for the production of M-Drol capsules.

- n. In or about December 2010, Steve Wood caused 15 kilograms of raw drug powder for the production of H-Drol capsules and a check in the amount of \$10,739.25 payable to "Human Tech" to be shipped to SITESH BANSI PATEL, in California.
- o. On or about January 6, 2011, SITESH BANSI PATEL sent an email to Steve Wood stating "*Whatever is fair to you is fair to me. I'm trying to keep my name out as much as possible, but want to make sure you guys are getting what you need.*"
- p. On or about January 20, 2011, after receiving a cash payment which had been mailed to him from Steve Wood, SITESH BANSI PATEL sent an email to Steve Wood stating in part "*. . .Received the bottle-thank you very much and it is very appreciated! And yes, it is beyond fair!*"
- q. On or about March 9, 2011, Steve Wood caused a cashier's check made payable to "Human Tech" in the amount of \$23,320.40 to be sent to SITESH BANSI PATEL, in California, as payment for the encapsulation of M-Drol and/or H-Drol raw drug powders. Subsequently, this check was deposited to the Bank of American checking account of GUILLERMO RAMOS/Human Tech.
- r. On or about April 22, 2011, Steve Wood caused two cashier's checks payable to "Human Tech" in the amounts of \$23,324.68 and \$12,765.00 and an unknown amount of cash to be sent to SITESH BANSI PATEL, in California, as payment for the encapsulation of drugs. Subsequently, the two cashier's checks were deposited to a Bank of American checking account belonging to GUILLERMO RAMOS/Human Tech.
- s. On or about August 29, 2011, Steve Wood caused the issuance of a First Citizen's Bank cashier's check in the amount of \$11,000 made payable to Human Tech for the

encapsulation of M-Drol and/or H-Drol raw drug powder. This cashier's check was deposited in the Bank of America checking account of GUILLERMO RAMOS/Human Tech.

4. All in violation of Title 18, United States Code, Section 371.

COUNT TWO

The Grand Jury charges that:

1. The Introduction and allegations set forth in Paragraph 3 of Count One are realleged and incorporated by reference.
2. At times from in or about 2008 through in or about August 2011, in the Western District of Virginia and elsewhere, SITESH BANSI PATEL, GUILLERMO "WILLY" RAMOS, Steve Wood, and others ("Conspirators") knowingly and willfully conspired to violate Title 18, United States Code, Section 1341, that is, having devised a scheme and artifice to defraud and for obtaining money by means of false representations, cause to be delivered by mail and private or commercial interstate carrier any matter or thing for the purpose of executing such scheme and artifice and attempting so to do.
3. It was part of the conspiracy that the Conspirators falsely represented H-Drol and M-Drol to be "dietary supplements" when, in fact, they were drugs. The Conspirators manufactured, labeled and sold H-Drol and M-Drol as "dietary supplements" and obtained money as a result of such representations
4. It was part of the conspiracy that Steve Wood placed orders with his source in China for the purchase of raw drug powders which were imported into the U.S. and encapsulated, bottled, and sold as dietary supplements.

5. It was part of the conspiracy that the Chinese source exported raw drug powders utilizing the international mail system and common carriers such as United Parcel Service to Steve Wood.
6. It was part of the conspiracy that the Chinese source caused the secretion of undeclared raw drug powders in the bottom of shipping containers to avoid detection and seizure by U.S. Customs and Border Protection authorities.
7. It was part of the conspiracy that the Chinese source caused the falsification of shipping manifests and international waybill mailing labels by falsely declaring the items were legal substances, when, in fact, they were raw drug powders, and the value was substantially less than the true amount paid.
8. On or about the dates listed below, in the Western District of Virginia and elsewhere, as part of the conspiracy and for the purpose of executing and attempting to execute said scheme and artifice to defraud and to obtain money by means of materially false and fraudulent pretenses and representation, the Conspirators caused to be delivered by mail and private or commercial interstate carrier any matter or thing for the purpose of executing such scheme and artifice and attempting so to do:

DATE

August 16, 2011

August 23, 2011

August 29, 2011

9. All in violation of Title 18, United States Code, Section 1349.

COUNTS THREE THROUGH FIVE

The Grand Jury charges that:

1. The Introduction and allegations set forth in Paragraph 3 of Count One and Paragraphs 3 through 8 of Count Two are realleged and incorporated by reference.
2. At times from in or about 2008 through in or about August 2011, in the Western District of Virginia and elsewhere, SITESH BANSI PATEL, GUILLERMO “WILLY” RAMOS, Steve Wood, and others (“Conspirators”), having devised a scheme and artifice to defraud and for obtaining money by means of false representations, causing to be delivered by mail and private or commercial interstate carrier any matter or thing for the purpose of executing such scheme and artifice and attempting so to do.
3. It was part of the scheme that that the Conspirators falsely represented H-Drol and M-Drol to be “dietary supplements” when, in fact, they were drugs. The Conspirators manufactured, labeled, and sold H-Drol and M-Drol as “dietary supplements” and obtained money as a result of such representations.
4. On or about the dates listed below, in the Western District of Virginia and elsewhere, for the purpose of executing and attempting to execute said scheme and artifice to defraud and to obtain money by means of materially false and fraudulent pretenses and representations, the Conspirators caused to be delivered by mail and private or commercial interstate carrier any matter or thing for the purpose of executing such scheme and artifice and attempting so to do:

<u>COUNT</u>	<u>DATE</u>
THREE	August 16, 2011
FOUR	August 23, 2011

FIVE

August 29, 2011

5. All in violation of Title 18, United States Code, Section 1341.

NOTICE OF FORFEITURE

1. Upon conviction of one or more of the felony offenses alleged in Counts Two through Five of this Indictment, the defendants shall forfeit to the United States:

- a. Any property constituting, or derived from any proceeds obtained, directly or indirectly, as a result of said offenses, pursuant to 21 U.S.C. 853(a)(1); and
- b. Any property used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of said offenses, pursuant to 21 U.S.C. 853(a)(2).

2. The property to be forfeited to the United States includes but is not limited to the following property:

\$175,000 in U.S. Currency

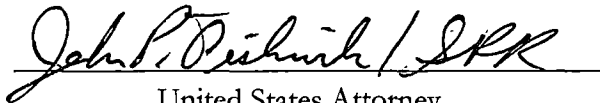
3. If any of the above-described forfeitable property, as a result of any act or omission of the a defendant

- a. cannot be located upon the exercise of due diligence;
- a. has been transferred or sold to, or deposited with a third person;
- b. has been placed beyond the jurisdiction of the Court;
- c. has been substantially diminished in value; or
- d. has been commingled with other property which cannot be subdivided without difficult,

it is the intent of the United States to seek forfeiture of any other property of the defendant up to the value of the above-described forfeitable property, pursuant to 21 U.S.C. 853(p).

A true bill, this 26th day of July, 2016.

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United States Attorney

/s/ Grand Jury Foreperson